The Journal
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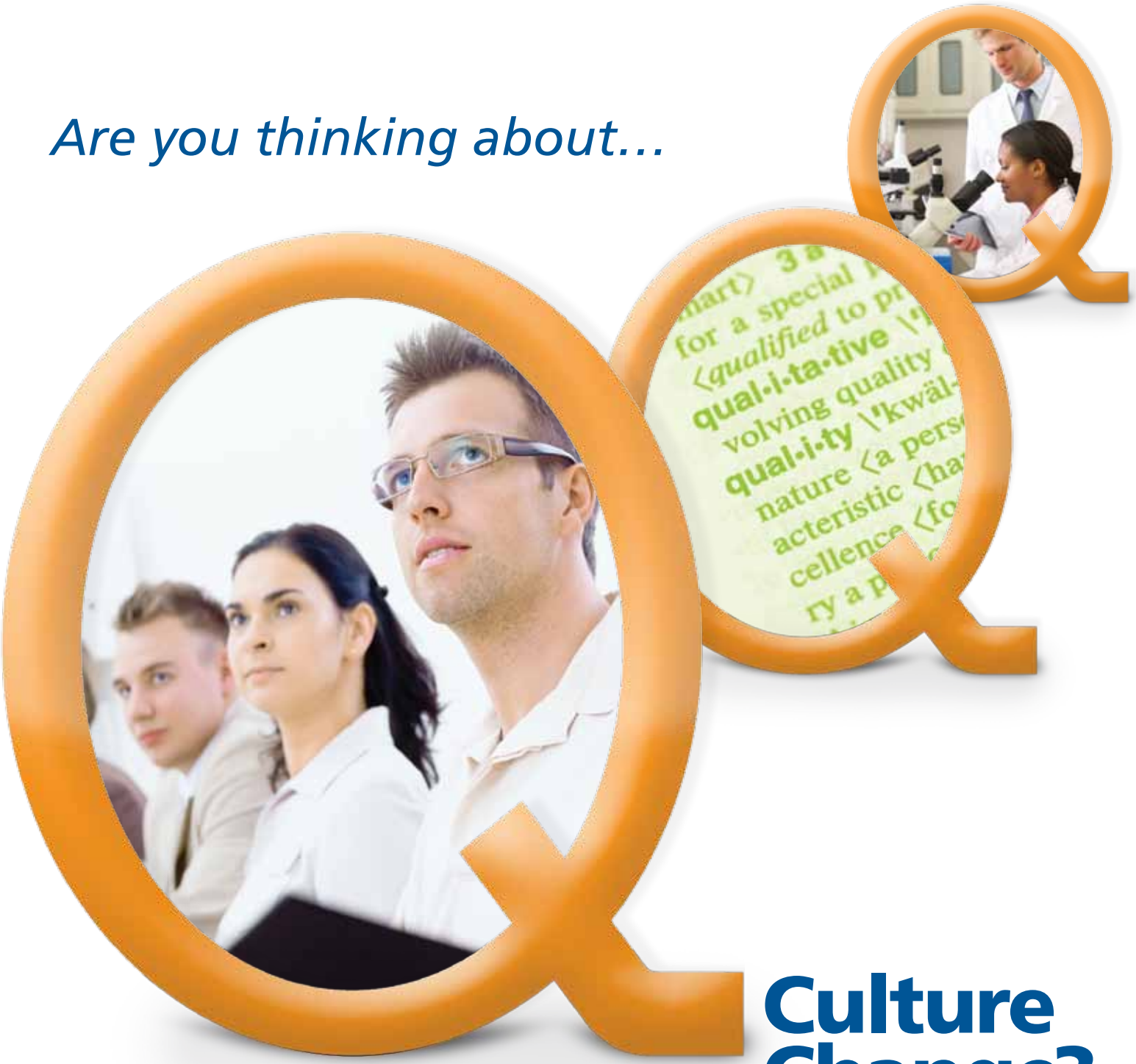
Are you thinking about...



Culture Change?

NSF DBA℠
Part of NSF Health Sciences
www.nsf-dba.com

welcome

Bob Pietrowski
Managing Partner
NSF-DBA

Welcome to the latest edition of the NSF-DBA Journal. We hope you enjoy reading the articles, comments and observations on the industry we serve. The theme of this edition is 'Facilitating Change'.

Our objective when we work with our clients is to bring about change. We aim to leave our clients better than we found them – perhaps better aware of the rapidly changing regulations that govern our industry, better aware of their strengths and areas for improvement and, most of all, better motivated to build on those strengths and to improve in those areas where improvement is needed.

We live in changing times and the pace of change is accelerating day-by-day. Those companies which embrace change will succeed in an increasingly competitive world, whilst those which don't will be left behind. We have helped many companies to embrace change and we have watched them improve and prosper as a result.

Change can take many forms – changes in facilities, equipment, processes, procedures, people and corporate culture. Most of these changes are relatively easy to achieve – all they take is time and money! The hardest change to make is the change in culture, but it is by far the most important, as without it many of the other changes are just window dressing and, most importantly, impermanent. There is an old joke, "How many psychiatrists does it take to change a light bulb?" Answer – "First the light bulb has to want to change". The same philosophy applies to culture change. That is why we work with people at all levels (starting with senior management) to bring about lasting culture change within organisations. So far, the results have been impressive, whether we are working with small companies wishing to improve Quality Assurance and relations with regulatory agencies or multinational companies wishing to empower staff at all levels to take ownership of Quality, and those companies who have used us keep inviting us back.

As you will see from the articles, we have helped companies to achieve lasting change through consultancy (as evidenced in Ron Johnson's article) and through training and education; both through residential courses such as QP training and via tailored in-house education programmes.

We believe we can help you too. If you are interested in discovering how we can change the culture in your company for the better, please contact us. We are here to help.

Lastly, to show you that we practise what we preach, we are going through change ourselves. Over the coming year we shall be aligning the various services offered by ourselves, Becker & Associates, NSF Pharmalytica, NSF Reference Standards and NSF Dietary Supplements into a single division to better serve our clients in pharma/biotech, medical devices and nutraceuticals/dietary supplements. The formation of NSF Health Sciences will mean the eventual loss of company names such as DBA and Becker, but only the names will change; quality of service and what we stand for will never change – they are not negotiable! We will keep you informed of progress through future editions of the Journal.

Bob Pietrowski
Managing Partner

NSF DBA℠
Part of NSF Health Sciences

Quality Culture For The 21st Century

Is your Quality Culture Fit for Purpose?

Want to find out?

by Martin Lush

If you Google 'culture' be prepared for days of reading. Let's just say, for the sake of expediency, that ***culture is defined by the actions taken, under pressure, when nobody is looking***. Like a moral compass, your Quality Culture keeps you heading in the right direction no matter how stormy and unpredictable the weather. With Consent Decrees, Warning Letters, fines and prosecutions running into $billions, the Quality Culture of some pharma companies, including some big players, is not what it needs to be. Their compasses are clearly pointing in the wrong direction. So how is your compass? Do you have a Quality Culture capable of navigating a chaotic and unpredictable 21st century?

To find out, grab a few colleagues and complete the following tasks. They will only take a few minutes. Tackle each as if your jobs depended on them. You never know…

TASK ONE: Time for Reflection

Let's start with a 'Quality Culture Health Check'. Answer the following with a simple yes/no:

- Frustrated by your hierarchy? Yes ☐ / No ☐
- Suffocated by your bureaucracies? Yes ☐ / No ☐
- Exhausted by internal politics? Yes ☐ / No ☐
- Management not walking the talk? Yes ☐ / No ☐
- Decision making ponderous and slow? Yes ☐ / No ☐
- Insufficient training budget? Yes ☐ / No ☐
- Management obsessed by profit alone? Yes ☐ / No ☐
- Suffering from 'death by measure'? Yes ☐ / No ☐
- Change control system slow, complex and unwieldy? Yes ☐ / No ☐
- SOPs and documents complex and impossible to follow? Yes ☐ / No ☐
- Do crisis and fire fights dictate your agenda? Yes ☐ / No ☐
- Absence of visible and approachable leadership on the shop floor? Yes ☐ / No ☐
- Suffering from initiative overload, trying to do too much? Yes ☐ / No ☐
- Staff turnover or attrition greater than 5%? Yes ☐ / No ☐
- 30-day time limit for closure of deviations? Yes ☐ / No ☐

A 'yes' to any and your culture is probably not fit for purpose. A 'yes' to many? Well, your compass (Quality Culture) is taking you in the wrong direction. You need to read on, your job may depend on it…

So, what does a good Quality Culture 'feel like'? Since NSF-DBA are lucky enough to have some of the finest consultants around, we asked 10 of our most experienced colleagues "what does it feel like when you walk into a company with a good Quality Culture?"

TASK TWO: The Honesty Test

This is what their combined 330 years' experience has taught them to expect. How do you measure up?

- A genuinely warm welcome from security and reception
- Demonstrable pride and ownership in everything at every level (the workplace, engineering workshop's documentation, the cafeteria). Everything says 'we care'
- An environment where people REALLY matter – contractors and agency staff as well as full-timers
- Minimal levels of hierarchy and bureaucracy
- A clean and well maintained plant. Not necessarily state of the art… just well looked after. From the toilets to the Class 100
- Leaders who are modest, visible, approachable, passionate, and informed. Leaders who care about what they do beyond the profit and loss account
- A culture that is open, transparent and focussed on excellent face-to-face communications
- Rigorous discipline. After all, when you have disciplined people, you don't need hierarchy, bureaucracy or excessive controls
- Excellence in the basics of GMP
- Patient-centric thinking at every level with excellence in risk-based decision making
- A very strong health and safety culture and ethos. GMP and health and safety are different sides of the same compliance coin. Both depend on positive behaviours and habits
- Low rates of turnover, typically less than 5%. People feel valued, engaged. They want to stay
- Confidence in junior staff and operators, the true custodians of quality. Clear accountability and ownership
- Total integration of QA on the shop floor. QA staff who understand the process and operators who understand the Pharmaceutical Quality System (PQS)
- Total congruency in objectives, actions, measures, rewards. No contradictions that confuse and drive the wrong behaviour. 'Quality is non-negotiable'
- An obsession with right first time and a passion for simplicity. An intolerance of waste and complexity
- Mistakes are genuinely seen as good opportunities for learning, personal development and improving profit
- Suppliers and third parties are considered 'one of the family'. An extension of the production line. Treated with respect and valued, not taken for granted

Best-In-Class Practices

Over the last 27 years NSF-DBA has worked in partnership with many clients to make their Quality Culture fit for the future, not the past. A 21st century Quality Culture doesn't just evolve or happen by accident. It is a product of disciplined focussed effort from

the top down. As one of our clients put it: "it's 98% perspiration, 2% inspiration". The gurus reckon 4-5 years of disciplined, painstakingly focussed effort is needed. Minimum. Although there is no such thing as a quick fix, we can help make your journey as painless as possible. During our many years of experience we have identified how the best-in-class created a Quality Culture fit for the 21st century.

How the Best Beat the Rest

The following is a summary of how the best achieved success. **You can find out more at our seminar on 'Quality Culture for the 21st Century' (see page 14).** For now just ask yourself how you compare with the behaviours and practices of market leaders:

1. Leadership: Those leading the way:

- Really 'get it'. They see the PQS as a business management system that extends across the product lifecycle, the entire business. It's considered a profit not a cost centre. The PQS is the engine that drives efficiency and improves quality as well as profit
- Firmly believe that if you do the right things profits will follow. Bad things happen to those who focus on profit alone
- Have a strong, visible CEO who demonstrably supports the PQS with the total commitment of their site leadership. Walking the talk is more important than emails
- Management are honest about where they are and where they need to be. Not, 'we've passed the last inspection…we're OK'. More, 'we were very lucky, now let's fix it'
- They have a broad understanding of the product lifecycle, not just the $ numbers
- Leaders who have a 'Value of Quality Story' they share at every opportunity. One that is personal, meaningful
  - 'Patients depend on us'
  - 'Take pride in making a difference'
  - 'Consequences of getting it wrong'
- They take a mature and intelligent approach to risk-based decision making
- They avoid the 'pendulum swing' when faced with a crisis. From doing too little to doing too much. They stay on course
- Accept full accountability. The buck stops here
- Standardise and then 'localise'. Set standards that provide a rules framework and then encourage local ownership by allowing local interpretation.

"Avoid bureaucracy and hierarchy by creating a culture of discipline, accountability without fear and ownership. Create a culture around freedom within a framework, rather than rules issued by central office that are inappropriate for most. Fill the culture with self-disciplined people. Disciplined people, disciplined thought, disciplined action"

– George Rathman, cofounder of Amgen

- Demonstrate (role model) the leadership behaviours they expect from others
- They invest in developing very strong local supervision
- Ensure there is a direct link between quality performance, incentives and rewards
- Success is celebrated and achievements rewarded, large and small

2. Company culture

- Open and blame-free. Problems are surfaced and sorted quickly, not hidden
- There is a 'see it, say it, solve it' mentality
- Attitude that quality extends across the product lifecycle. They design quality in from the start for their products, processes, systems and documents
- Transparency not secrecy
- 'Greater good beyond pure profit', not profit at all costs
- Excellent communication of the quality agenda supported by **positive** feedback on performance:
  - Face-to-face briefings for the entire workforce
- Team approach to deviation investigations and continuous improvement
- Congruency. Behaviours, actions, measures and rewards all driving the right behaviour
- A culture of continuous improvement, not continuous fire fighting

3. Do the basics to PhD level with a focus and passion for simplicity

- User involvement in the creation of user-friendly documents. SOPs with more pictures and schematics than words
- Batch records that are thin and functional with fewer check signatures
- Change control systems that are simple and fast
- A focus on simplifying the lives of the users, not the system administrators
- The KISS principle reigns supreme. Keep It Simple Stupid!

4. Organisation and people

- The best-in-class recruit people with the right values, attitudes and beliefs. 'You can train in the skills, it's difficult to change mindset'
- Induction process that gets across the vital importance of what they do
- Cross-functional career development. Manufacturing spend time in QA and vice versa
- QA representation on the executive board. After all quality is business critical
- Cross-functional teams and meetings. Manufacturing, QA, QC, Engineering, Technical support, Registration, Commercial etc. One team, with one purpose. No silos, fiefdoms or turf wars are tolerated
- Excellent internal customer/supplier relationships. People understand what others do
- Risk-aware across all activities. Everyone understands the consequence of 'getting it wrong'. Accountability for product quality, without fear
- Engagement of the entire workforce in quality improvement
- Extensive process expertise and knowledge

If you would like to discuss any of these services please

5. Company mantra 'we can always do better'. A hunger for continuous improvement across all business activities

- Mistakes are seen as learning opportunities, not an inconvenience
- Systems in place for sharing knowledge and 'lessons learned', the successes and the failures
- Acceptance of new ways of working, not 'we've always done it this way'

6. Risk management: intelligent, mature, integrated

- Mature approach based on process and product expertise not blind, risk-averse compliance. Best-in-class focus on the real risks rather than those imagined
- A standardised and fully integrated risk management process. Not one 'bolted on'
- Risk management is central to every business decision. From equipment calibration to due diligence
- Decisions based on science

7. Excellent change management: to focus resource, stay in control, and say NO!

- Change control is seen as core business competency, not a compliance activity
- Used to focus resource on the 20% of initiatives that contribute 80% benefit to quality and business performance
- Ensures a 'measured' rate of change. Not a chaotic stampede

8. Surveillance and escalation systems. Sensitive, robust, fast

- Governance structures in place to oversee performance and enforce standards
- Systems in place that allow data to be collected, interpreted and acted upon quickly. Hours not days, weeks not months to ensure action is taken before it's too late: data relating to
- Audits and self-inspections
- Deviation and CAPA
- Customer complaints
- Product quality reviews
- Batch rejects
- Reworks and reprocessing

9. Systems and measures that reinforce and habituate the desired behaviours

- Performance measures that drive the right behaviour
- Structures, processes and systems that reinforce desired behaviour, not destroy it
- Audits that offer solutions, not just criticism
- People encouraged to raise deviations, not punished
- SOPs that encourage compliance rather than making it impossible

10. Education and development: good quality people = good quality products

- Strategic investment and planning in education
- Education budget protected no matter what
- Focus on education, not training. Coaching, mentoring, not telling
- Internal 'Quality Leadership'
- Education for key decision makers
- Executive GMP education for senior executives
- Executive briefings. Staying up-to-date and ahead of the game

Key Points

- A company's Quality Culture is like its compass. It serves to guide it safely through an unpredictable world to a successful future, no matter how bad the weather
- Those suffering regulatory censure have Quality Cultures that are no longer fit for purpose. Their compass has taken them in the wrong direction
- Changing your Quality Culture takes strong leadership, company-wide engagement and disciplined execution
- The commercial and regulatory weather conditions are changing fast. Changing culture takes time and this precious commodity is fast running out. For the sake of all your stakeholders, don't get left behind!
- The good news is that others have done it. If you want to know more about their problems and pitfalls as well as their successes come along to our 'Quality Culture for the 21st Century' seminar. We will help you learn from the best
- Having the right Quality Culture will ensure that the Quality of your product remains non-negotiable, no matter what

"Quality is not an act. It is a habit." **– Aristotle**

contact Martin Lush, Senior Partner at mkl@nsf-dba.com

Organisational Culture…
The Achilles' Heel

by Ron Johnson – *NSF Becker Consulting*

Much of Becker Consulting's work involves assisting companies remedy flawed quality systems. This is usually done as a result of threatened or actual enforcement action by the Food and Drug Administration. In these circumstances, companies are desperate and willing to do 'whatever it takes' without a full understanding of what that means. While expansive in concept, 'whatever it takes', for many, means simply marshalling internal and external resources to design and document a new quality management system. While this is not an insignificant commitment, it unfortunately fails to consider the cause of the crisis, ie how did this happen? In our experience, the answer to this question is, universally, organisational culture. Failing to address this root cause in the remediation initiative foretells an unsuccessful outcome. Lack of success, in spite of a major commitment by the company, albeit a fatally flawed one, leads to frustration for management and employees…and the company's consultants. Worse, such a failure may lead to even more aggressive and draconian enforcement action.

Principles, values and beliefs shape the culture of a society just as they do in an organisation. The culture of an organisation drives employee behaviours. The best designed, most sophisticated quality systems can be subverted by employee behaviours driven by an organisational culture that is not aligned with quality doctrine. In some cases, undesirable behaviours are, unknowingly, incented by the organisation's own policies and programmes. FDA files are replete with companies that have invested millions of dollars attempting to comply with FDA quality system requirements, only to fail and succumb to FDA enforcement action. FDA attributes what it calls "corporate culture" as the root cause of most company compliance problems.

We, at Becker, possess the skills and methodology needed to help a company design and document a world class quality system. We also learned very early that this methodology must address the imperative of cultural alignment, lest our efforts and those of the company are for naught. Frankly, this is the most difficult part of a remediation project. Individuals are drawn to the healthcare industry by altruistic desires to help people. Consequently, healthcare companies are bewildered at the suggestion that their cultures may not support quality principles. Some are actually affronted by the notion. After all what healthcare company doesn't want to produce high quality products? It is no wonder that a company would challenge a consultant's suggestion that attention to the corporate culture is necessary.

During the remediation project, our consultants are on site working with the company to create a new system. During this time, we can be effective in counteracting the negative impacts of organisational culture. Once the system has been established and operated for a short period of time, we depart leaving full execution to the company. Recognising that an antagonistic corporate culture can have its greatest negative impact at this point, our overall approach is designed to address cultural issues early in the process. This enables the company to execute in a quality-supportive environment assuring them of ultimate success.

We encourage a self-assessment by company management of its policies and practices that influence employee behaviours. Organisational values and principles are established by the top of the organisation. While most companies have stated values supportive of quality objectives – the easy part – it is management's compliance with them that is determinative in influencing employee behaviours.

- Does management override the Quality Assurance Unit's decision to withhold product release?
- Does management cut funding of the quality function before, or to a greater extent than, others?
- Does management recognise and reward quality achievements as it does financial ones?
- Does management effectively balance its capitalistic imperatives and its commitment to quality?

Management's behaviour speaks volumes in communicating the company's 'real' values and, in turn, creates the company's culture. An integral element of our methodology addresses management's responsibility to 'walk the talk' and model the company's quality values. Among other things, we encourage each member of senior-most management to have at least one performance element related to quality. Our goal is that each member of the company's executive management team has as intimate a knowledge of the state of the company's quality system as it does its financial condition.

A company's rewards, recognition and bonus programmes are designed to promote employee behaviours in support of its company values. Execution of these programmes quickly enlightens employees that the company's real values are important and they react in kind. However, it is not uncommon to find that these programmes sometimes encourage wrong behaviours – those that do not support stated company values. For example, we have seen bonus plans that have rewarded employees for meeting regulatory market clearance and product launch milestones. When these milestones are met, everyone celebrates and employees are duly rewarded. Yet, there is no accountability when the new product has to be recalled six months later because of design and/or manufacturing defects. This misalignment communicates the company's priorities, ie obtaining market clearance is more important than assuring product quality. Other personnel practices such as salary adjustments, promotion, informal recognitions, etc can similarly incent inappropriate behaviours.

A company's ability to effectively develop and successfully implement an effective quality management system is reliant on a supportive organisational culture. Those who do not incorporate a cultural evaluation when re-engineering quality systems risk failure. Creating competent systems on paper is pretty straightforward. Employee behaviours during execution can trump the best designed system.

QP Qualified Person & Professional Development Training Update

Mike Halliday never gets bored of jumping on the train for change!

One of the things I really enjoy is running our QP free seminars. These are designed to help those who are considering becoming a QP to understand what's involved regarding starting requirements, the process, training options and workplace support. I usually ask one of our former delegates to give a personal case study of their own experience. I recall at one such event this former delegate told the prospective students, "warn your company they won't get back from the course the same person they sent!" It was no joke, she was deadly serious! Her journey and development through the process changed her. She transformed from someone who worked in quality and was led by others, to a real quality leader in her company. She had knowledge and wasn't afraid to use it!

This is a journey I see often as a personal tutor to many delegates through the course. The quiet reflective type, the shy, the boisterous and those ambivalent to change – we give them knowledge and plenty of practice in applying their learning in work-based problem solving. They have the opportunity to lead groups and contribute to groups – the learning is continuous!

This was evident in the recent formulation and processing module where the teams were working hard on risk-based problem solving and after one exercise I asked, in a reflective style, "who contributed to the team work and who sat back?" No answers were needed but the next exercise had everyone contributing. The quiet contribute and the noisy learn to listen.

Congratulations to our recent QP successes:

- **Linden Stead**, Piramal Healthcare
- **Adam McLennan**, AstraZeneca Pharmaceuticals
- **Laura Matthys**, Reckitt Benckiser Healthcare (UK) Ltd

The QP programme covers practical decision making, and the delegates are shown that the steps need be no more complex than:

- What is the issue?
- What is the risk to the patient?
- What is the compliance risk?
- Is there a risk to the business?
- Do you have enough information?
- What more is needed and from whom?
- Have you made a decision?
- And who do you tell?

As well as these simple steps, the delegates quickly develop their own problem solving 'mantras'. They practice decision making skills; they learn to use influencing and communication skills effectively.

On the QP programme we add soft skills sessions to help graduates from the programme communicate and influence, in other words to help them apply the knowledge they have been given on the course effectively in the workplace. QPs need to have a voice!

The QP programme is designed to change people. Knowledge brings confidence – skills and practice in decision making build leaders. It really is little wonder that companies bring this training in-house to develop a culture change and to build a cadre of leaders. As my past student said, "don't send a poodle to the course expecting a poodle to return!"

So when I attend the QP seminar I do not just see young hopeful professionals, I see an opportunity for change and growth for the individual and also for an organisation. They are joining the route for change.

Our next Seminar for Prospective QPs and Sponsors is on 14 May at the York Marriott Hotel, York. Come along – it's FREE, or you can contact Mike directly on mch@nsf-dba.com to find out more information about this and other QP training ideas.

One of our popular QP courses is Quality Management Systems, join us to find out more on 8-12 April in York.

Industry News

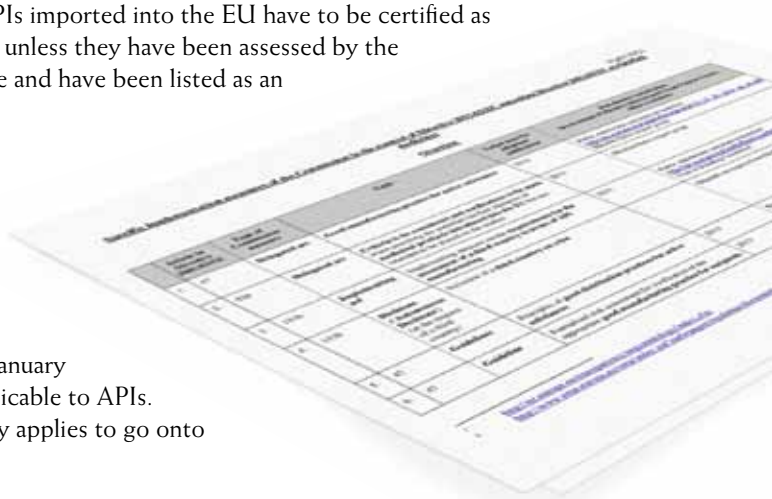
by Pete Gough

EU Pharma News

Implementation of the Falsified Medicines Directive (FMD)

The FMD, Directive 2011/62/EU, requires that from 2 July 2013 all APIs imported into the EU have to be certified as meeting EU GMP by a Competent Authority of the exporting country unless they have been assessed by the European Commission as having acceptable regulatory controls in place and have been listed as an acceptable country.

As of the end of January 2013 the only country which the Commission had approved, and will not require their APIs to be certified, was Switzerland. Six other countries have applied to go onto the list of acceptable countries and are in the process of being assessed: Australia, Brazil, Israel, Japan, Singapore and the United States of America.



The Commission has published an 'Implementing Decision', dated 24 January 2013, on the assessment of a third country's regulatory framework applicable to APIs. This provides confirmation of the criteria to be assessed when a country applies to go onto the Commission's list of acceptable countries. The criteria are:

- The GMP standard being applied is equivalent to that given in Part 2 of the EU GMP Guide; ie ICH Q7
- The inspection resources, the qualification and training of inspectors, inspection procedures, inspection strategies and mechanisms to address conflicts of interest, inspection performance standards, enforcement powers, alert and crisis mechanisms, and analytical capacity taking into account the applicable EU GMP guidelines
- The third country's arrangements in order to ensure regular and rapid provision of information by the third country to the EU in relation to non-compliant producers of active substances

On 28 January 2013 the Commission published version 3 of their Q&A regarding the importation of APIs from outside the EU and version 2 of the certification template. The changes are only minor, with just three changes to the Q&A and the addition of the inspection authority (if different from the issuing authority) to the template.

In mid-January 2013 India announced that the Central Drugs Standard Control Organisation (CDSCO), through the Drugs Controller General of India (DCGI), had been appointed as the competent authority to issue the certificates for API exports to Europe. The Indian API industry has expressed reservations over the speed with which the DCGI can sanction the certificates and some officials have also raised concerns over the accountability of the competent authority in case EU regulators find fault with any of the consignments.

Industry
News

EU GMP Guide Part 1

Draft Revision of Chapter 3 (Premises and Equipment)

On 17 January the Commission published a draft revision of Chapters 3 and 5 to address the management of the risks of cross-contamination in shared manufacturing facilities. This issue had been the subject of debate within the EU inspectorates for the past 10 years. The new approach that is contained in these drafts is risk-based and includes a toxicological evaluation of the potential risks. This represents a major shift in the currently accepted way of calculating cleaning validation acceptance limits and whether or not dedicated facilities are required.

The draft Chapter requires that Quality Risk Management principles should be used to assess and control cross-contamination risks. Risk assessments should include, amongst other parameters, a toxicological evaluation of the products being manufactured and refer to the Guideline on setting health-based exposure limits (see later).

Draft Revision of Chapter 5 (Production)

In November 2010 the Commission published a draft revision to Chapter 5 of the EU GMP Guide. A further draft of Chapter 5 was issued for comment on 17 January 2013. This new draft contains changes to sections 17 to 20 to improve the guidance on prevention of cross-contamination and to refer to toxicological assessment guidance. Changes were also introduced in sections 26 to 28 on the qualification of suppliers in order to reflect the legal obligation of manufacturing authorisation holders to ensure that active substances are produced in accordance with GMP. The changes include supply chain traceability. Section (33) is inserted to clarify and harmonise expectations of manufacturers regarding the testing of starting materials, while section (68) introduces guidance on notification of restrictions in supply.

Guideline on setting health-based exposure limits

The 'Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' that is referred to in the proposed revisions to both Chapters 3 and 5 was published as a draft for comment on 8 January 2013.

This guideline attempts to provide a more scientific approach to the setting of acceptance limits. For the past 25 years the generally accepted method for setting the acceptable level of carryover has been the lower of either no greater than 1/1000th of the lowest clinical dose of the contaminating substance in the maximum daily dosage of the next product or a maximum contamination of 10 ppm of the previous active substance in the next product manufactured. These limits do not take account of the available pharmacological and toxicological data and may be too restrictive or not restrictive enough.

The approach outlined is based on the calculation of health-based exposure limits and is very similar to that given in the ISPE 'Baseline Guide' on the subject of 'Risk-Based Manufacture of Pharmaceutical Products (RISK-MaPP)' that was published in September 2010.

Revision of Chapter 6 (Quality Control)

A draft revision of Chapter 6 was published on 17 January 2013. This revision adds more emphasis to the need to investigate Out Of Specification (OOS) and anomalous results and Out Of Trend (OOT) results. The need for a procedure for OOS/OOT results is added to the documentation section and the requirement that "Any out of trend or out of specification data should be addressed and subject to investigation" is added.

The principal changes introduced by this revision are around requirements for test method validation and transfer. The need to verify test methods that were not originally validated by the laboratory using them (eg pharmacopoeial methods) has been added, as has the requirement for reference standards to be certified, qualified and verified as suitable for the intended use. A whole new section on 'technical transfer of testing methods' has been added.

European Commission issues three draft documents for comment:

1. Guideline on GDP for APIs for Human Use

At just seven pages this draft is, mercifully, much shorter than the 30 page draft EU GDP for Finished Products that was issued in July 2011 (and which has still not been finalised).

2. Guideline on the formal Risk Assessment to determine the appropriate GMP for Excipients (as required by the Falsified Medicines Directive, 2011/62/EU)

This draft guidance consists of three main sections:

Section 2: 'Determination of appropriate GMP based on type of excipient' provides guidance on how to assess and rank the risk presented by the excipient.

Section 3: 'Determination of Excipient Manufacturer's Risk Profile' covers identification of appropriate GMP and assessment, ranking and control of the risk profile of the excipient manufacturer.

Section 4: 'Confirmation of Application of Appropriate GMP' presents guidance on how to manage the risks of use of the excipient on an ongoing basis.

3. Template for QP's Declaration of GMP Compliance for IMPs manufactured in non-EU countries

This is a simple two-page template. The declaration can be made on the basis of either a personal audit by the QP or an audit conducted by a third party (which includes audits by other QPs employed by the same company). If the manufacturing site has not been audited a justification as to how the QP knows that the site meets EU GMP has to be provided.

Pete will be delivering a Pharmaceutical Legislation update course in Manchester on 9 April. Come along and get all the latest industry news.

Forthcoming Courses

What's planned for March – June 2013

Risk-Based Decision Making for Quality Professionals and QPs

Amsterdam Marriott Hotel, Amsterdam, The Netherlands

5 – 6 March

The toughest task facing any QP or quality professional is to take decisions regarding the suitability for release of materials when things go wrong. This course is designed to provide you with proven risk management techniques which will help you to make sound, risk-based decisions which benefit the patient, your company and you! Packed with real life scenarios for you to work on, this course is not to be missed.

Course Fee: £1400.00 plus VAT

Deviation and CAPA Systems – Best Practices

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

11 – 12 March

How good is your Deviation and CAPA system… or are you at RISK?

Your Deviation and CAPA system is a crucial part of your quality system. It should protect your patients against poor quality medicines and drive continuous quality improvement by stopping inefficient, wasteful and often dangerous practices. This course is not just about how to conduct a root cause investigation. It is much, much more.

Course Fee: £1400.00 plus VAT

Formulation & Processing (Part 2)

Qualified Person & Professional Development Training

Hilton York Hotel, York, UK

11 – 15 March

This course focuses on sterile dosage forms, inhalation products and topical products. The production of sterile products is highly demanding and much of the course is devoted to the facility and control issues which impact product quality and patient safety for sterile products. Formulation challenges are reviewed for each product type. Case studies are presented for group discussion and learning. It is an ideal in-depth course for those involved in the production, oversight and control of sterile products and inhalation products.

Course Fee: £3200.00 plus VAT (First booking)
£2560.00 plus VAT (Additional bookings from same site)

Human Error Prevention

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

13 – 15 March

Human error is often thought to be the cause of many product recalls, customer complaints, batch rejects, deviations and adverse audit findings. In most cases, however, human error is not the root cause, just a convenient excuse.

The good news is that such costly and risky mistakes can be prevented. The objective of this course is simple – to provide you with very practical advice and guidance on how to significantly reduce so called 'human error'. Error reduction will potentially save you £millions and improve your regulatory compliance. Don't allow yourself to fall behind your competitors!

Course Fee: £1800.00 plus VAT

Quality Management Systems

Qualified Person & Professional Development Training

Hilton York Hotel, York, UK

8 – 12 April

We all know that the quality of your products depends on the quality of your people and the effectiveness of your Quality Management System (QMS). In fact, as QPs and quality professionals, you can't release product and stay in business unless your QMS is 'in control'. This is easier said than done. Supply chains are more complex than ever before and you are being asked to do more with less, and faster! This course will provide you with answers to some really tough questions.

Course Fee: £3200.00 plus VAT (First booking)
£2560.00 plus VAT (Additional bookings from same site)

Pharmaceutical Legislation Update:

Continuing Professional Development for Qualified Persons & Technical Personnel

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

9 April

This short course will keep you right up-to-date with the latest changes to EU, ICH, PIC/S, FDA and UK pharmaceutical regulations and the latest proposals for future changes. Additionally, we will provide practical advice on how best to comply!

Course Fee: £700.00 plus VAT

Visit www.nsf-dba.com for more information on all our courses

Course details and prices are correct at the time of printing and are published in good faith. NSF-DBA reserves the right to make any changes which may become necessary.

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Pharmaceutical GMP

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

15 – 18 April

Europe's most popular GMP course!

It is a legal requirement that all staff receive regular training in Good Manufacturing Practice. This course is designed to provide you with up-to-date knowledge of new and impending GMP regulations and current 'hot topics'.

- This course repeatedly achieves the highest customer satisfaction level of any of our courses, with 95% of delegates rating it "very good" or "excellent"
- This course now forms an entry level GMP training requirement for our very popular Pharmaceutical Quality Management Systems Auditor/Lead Auditor training course

Course Fee: £2400.00 plus VAT

Pharmaceutical Microbiology

QP

Qualified Person & Professional Development Training

York Marriott Hotel, York, UK

13 – 17 May

Microbiological contamination of products and processes continues to be a major concern to the industry and its regulators. The potential impact of such contamination can be catastrophic. Put simply, microbial contamination can kill your patients and your business! This course, for non-biologists and microbiologists, is designed to provide you with the knowledge, confidence and decision making risk assessment skills to prevent this happening.

Course Fee: £3200.00 plus VAT (First booking)
£2560.00 plus VAT (Additional bookings from same site)

Free Seminar for Prospective QPs and Sponsors

FREE SEMINAR

York Marriott Hotel, York, UK

14 May

Since 1990, NSF-DBA and the University of Strathclyde have collaborated to present a structured modular course designed for people wishing to become a QP. This course is now recognised as the most successful and main route to QP education in the UK and increasingly in Europe.

Please attend this Free Seminar if:

- You are planning to train to become a QP
- You are interested in maximising your technical knowledge and value to your organisation
- You are responsible for QP training or technical development
- You want to know more about sponsoring a QP

Please Note: This seminar is open to sponsors and prospective sponsors of candidates currently studying or planning to study with NSF-DBA or any other training provider.

Best Practice for the Analytical Laboratory

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Analytical Methods: Documentation, Validation & Transfer

13 – 14 May

Quality Control (QC) laboratories perform a vital role within Good Manufacturing Practice. They provide the data upon which critical decisions, such as batch release and the stability of products, are based. This course aims to give you an overview of current best practices for the development, documentation, validation and transfer of analytical methods for use in QC laboratories. It is also designed to provide you with practical advice and detailed guidance on analytical method validation, based on the ICH Q2 guideline and on pharmacopoeial method verification, based on USP general chapter 1226.

Course Fee: £1400.00 plus VAT

How to Audit – QC Chemical Laboratories

How to Audit

15 – 16 May

This course is designed to provide existing auditors with the necessary technical detail to enable them to effectively audit a quality control (QC) chemical laboratory to ensure that both EU and FDA GMP requirements are met. It is ideal for delegates who have either previously attended NSF-DBA's IRCA certified Pharmaceutical Quality Management Systems Auditor/Lead Auditor course or who already have a good understanding of the basic principles and practices of auditing and wish to expand their technical understanding of good QC laboratory practice. The course can also contribute to registered Auditor's and Lead Auditor's professional requirement for continuing professional development (CPD).

This course will also be ideal for personnel who work within a QC chemical laboratory and who wish to learn how to conduct comprehensive self-inspections.

Course Fee: £1400.00 plus VAT

Investigating Out of Specification Results

17 May

The way a company responds to Out of Specification (OOS) and Out of Trend (OOT) results is a key part of GMP. The draft revision of EU GMP Chapter 6 requires that OOS, OOT and anomalous results be investigated and that there be an SOP to cover this process. However, it is an area of GMP in which companies still fail to meet regulatory expectations. This course is based on both the 2006 US FDA and 2010 UK guidance on OOS and OOT investigations. This course is designed to provide you with practical advice on how to investigate OOS results and make appropriate decisions, which will meet regulatory expectations and add real value to your business.

Course Fee: £700.00 plus VAT

Get in touch now to book your place on any of these courses
Call us on: +44 (0) 1751 432 999 or email: courses@nsf-dba.com

Forthcoming Courses

What's planned for March – June 2013

Effective Pharmaceutical Audits and Self-Inspections (PQMS Auditor/Lead Auditor)

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

20 – 24 May

Faced with industry and regulatory pressure, NSF-DBA was actively encouraged to successfully redesign an existing, popular course and reintroduce it with the first International Pharmaceutical Quality Management Systems Auditor/Lead Auditor Qualification. This course has been specifically designed to provide delegates with education, understanding and development to meet today's pharmaceutical pressures, including the auditor skills and toolbox of auditing techniques needed by the successful pharmaceutical lead auditor. Given the course focus, content and delivery of EudraLex Volume 4 Chapters 1 to 9, ICH Q10 as the combined QMS, the team at NSF-DBA sees this as the first truly certified GMP auditor training course available globally today.

Course Fee: £2600.00 plus VAT

How to Audit – Bulk Biotech Operations

York Marriott Hotel, York, UK

21 May

This short course is designed to prepare you to conduct your first audit of bulk biologics manufacture. We will outline the general process, indicate quality critical steps and provide you with the key questions to ask (and answers to expect!) when auditing facilities, cell banking, cell cultivation, harvesting, purification steps, cleaning, environmental control, bioburden management, QC activities and much more.

Course Fee: £700.00 plus VAT

How to Audit – Sterile Filling Operations

York Marriott Hotel, York, UK

22 May

We will be running this highly interactive course with the objectives of:

- Reminding auditors of the key legislation and guidance around auditing sterile operations
- Developing audit plans and agendas for sterile audits that work
- Working through case studies and audit observations to discuss severity ranking and references to support the findings

Course Fee: £700.00 plus VAT

Sterile Products Manufacture

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

3 – 6 June

Sterile products manufacture represents the most hazardous activity (to the patient!) performed by pharmaceutical companies. This is why it attracts so much regulatory scrutiny! Recent regulations and guidelines from EU (Annex 1) and FDA (Sterile Drug Products Produced by Aseptic Processing) are confusing to many and very difficult – and expensive – to comply with in full. This course is designed to help you comply with these and other documents in a way that is practical, scientifically sound and cost-effective. This is by far the most popular of our courses – hundreds of people attend it every year, either through this residential course or via courses run in their companies – and delegate feedback is excellent!

Course Fee: £2400.00 plus VAT

How to Audit – Manufacture and Control of Investigational Medicinal Products

York Marriott Hotel, York, UK

4 June

It is a challenge for the industry and for auditors to know where GMP audits end and where GCP audits begin. In fact there is no clear dividing line. There is a great deal of overlap between GMP and GCP and this needs to be understood. Auditors faced with performing their own internal audits or audits of contractors handling IMPs have many questions. This one-day course will attempt to answer all of these questions in a practical way so that delegates have materials they can use in their IMP auditing work.

Course Fee: £700.00 plus VAT

QP Alumni Meeting

York Marriott Hotel, York, UK

6 – 7 June

The annual meeting organised by the NSF-DBA QP Alumni Association, where former NSF-DBA trainees gather to discuss topics of key importance to practising QPs. A meeting for QPs, organised by QPs!

Meeting Fee £450.00 plus VAT

Risk-Based Decision Making in Sterile Products Manufacture

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

10 – 13 June

Manufacturing sterile products is easy – until things go wrong! When things go wrong catastrophically, decision making is relatively straightforward. However, things are rarely so 'black and white'. The biggest challenge facing anyone in sterile products manufacture is to deal with the 'grey area' problems which arise almost daily. This unique course is designed to help YOU do just that!

Course Fee: £2400.00 plus VAT

Visit www.nsf-dba.com for more information on all our courses

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Modern Approaches to Process Validation

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

10 – 13 June

This course will focus on the modern approaches to process validation, including the design of facilities and the qualification of equipment and utilities. It will provide practical advice on implementing the 2011 FDA guidance and the 2012 draft EU CHMP guidance on process validation. We will explain how process validation must link to patients' needs and the changing regulatory requirements. We will explain how tools, such as risk management, statistics and change management, are used to accomplish this. We will show how this modern approach can add real value to your business and provide better protection to patients.

Course Fee: £2100.00 plus VAT

GMP for Clinical Trials Manufacture and Supply

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

10 – 13 June

The implementation of Directive 2001/20/EC has brought profound changes to the way clinical trials are conducted in the EU and equally important changes to the way IMPs are manufactured and controlled.

- What 'standard' of GMP is appropriate at the various clinical trial phases?
- Validation – how much, how soon?
- What exactly is a Product Specification File?
- In the case of split manufacture, whose QP should release?
- What is the role of the QP when IMPs are imported?
- Where does GMP end and GCP begin?
- How do QPs deal with comparators?

All of these questions and many more will be addressed in this intensive four-day training course.

Course Fee: £2400.00 plus VAT

Active Pharmaceutical Ingredients

Qualified Person & Professional Development Training

Durham Marriott Hotel Royal County, Durham, UK

17 – 20 June

The quality of a medicine depends in no small part on the quality of its ingredients, and in particular the active. Thus, the QP and other key professionals in dosage form manufacture must have a thorough understanding of how the manufacture and control of the active and its supply chain may influence the fitness for use of the finished product. This is recognised by the regulators, especially in Europe where the adoption of Directive 2004/27/EC has put the responsibility for assuring the quality of the active firmly on the shoulders of the dosage form manufacturer, with certain expectations specifically for the QP. This course is designed to provide you with the knowledge and understanding to fulfil your responsibilities.

Course Fee: £2560.00 plus VAT (First booking)
£2048.00 plus VAT (Additional bookings from same site)

Implementation of Falsified Medicines Directive: Supply Chain Assurance

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

18 June

The current complexity of the global supply chain now presents many challenges and threats to the quality of medicines and the ability of pharmaceutical companies to deliver them at the right time and the right price to the patient. The EU Falsified Medicines Directive and the revised EU GDP Guideline seek to address a number of these issues and to improve the security of the supply chain, in a more integrated way. The course will cover the requirements for the manufacturer, packager, QP/QA department, distribution network, brokers, and wholesaler dealers. It will also seek to identify and discuss the practical implications to all the stakeholders in the supply chain.

Course Fee: £700.00 plus VAT

Implementation of Falsified Medicines Directive: Anti-Counterfeit Safety Features

Manchester Marriott Victoria & Albert Hotel, Manchester, UK

19 June

The current complexity of the global supply chain now presents many challenges and threats to the quality of medicines and the ability of pharmaceutical companies to deliver them at the right time and the right price to the patient. Counterfeiting of medicines is a lucrative opportunity for organised crime, and is growing at an alarming rate globally. The course will review the trends over the last ten years, the initiatives of the global security network, and the current regulatory requirements. It will also discuss existing and emerging technology to protect the patient and the reputation of the pharmaceutical industry from this ever increasing threat.

Course Fee: £700.00 plus VAT

Get in touch now to book your place on any of these courses
Call us on: +44 (0) 1751 432 999 or email: courses@nsf-dba.com

QUALITY CULTURE FOR THE 21st CENTURY

a new course for 2013 with MARTIN LUSH

Martin has worked in the pharmaceutical and healthcare sectors for over 30 years. During this period he has helped many companies navigate their way through the challenges that Warning Letters and Consent Decrees present. In his time with NSF-DBA he has developed a style for training that has earned him a reputation for creating interesting and participative training events. He understands what the learner needs and with his in-company work he has had a great opportunity to learn what makes an organisation successful and what hinders progress. These are some of the areas where he believes NSF-DBA has helped companies to achieve success.

Establishing and maintaining a Quality Culture fit for the 21st century takes strong leadership, disciplined execution and a lot of support. We work in partnership with our clients to create and maintain a culture that satisfies all stakeholders. Anyone who tells you culture change is quick, smooth and painless isn't telling the truth. It takes years and rarely goes according to plan. When stuff happens we stick with you. With over 27 years of global experience in culture change we know what works and what doesn't.

Customised Quality Leadership Education Programmes

Culture change without education is impossible. Not training, but customised educational programmes that change the way people think and act. NSF-DBA's unique style of education is designed to change behaviours, not just provide information.

Best-In-Class Practices: Don't Reinvent the Wheel

Culture change is tough but achievable. NSF-DBA has worked with many organisations that got it right. We can help you learn from their successes (and their mistakes) so you don't waste time reinventing the wheel. The best-in-class practices summarised in the earlier article are just the tip of the iceberg!

Consultancy Support

We are fortunate to have some of the most experienced consultants available. With a minimum of 25 years' hands-on industry experience they can gauge your culture within hours by what they observe and the people they meet. Having been in your shoes they also understand what works in the real world.

Regulatory and Industry Updates

To know if your compass is pointing in the right direction you need to understand the weather you have to navigate. In short, the industry and regulatory challenges on the horizon. We keep our clients informed about what's coming and, importantly, what course to steer.

Executive Briefings

Culture change without informed leadership simply doesn't happen. These 1:1 briefings are designed to be short, sharp and to the point. After all we recognise you are busy people. We provide an easily digestible assessment of the global regulatory challenges and the best-in-class practices for leading culture change. Leading culture change is lonely and nerve-wracking. These briefings provide a safe haven to examine concerns, generate solutions and provide support.

This is just a snippet – come along to Martin's course on 1-3 October 2013 in Manchester and really get a better understanding of what you need to consider if you want to prepare for today's Quality Culture challenges!

How Good is Your Pharmaceutical Quality System?

Does your PQS comply with the requirements of ICH Q10? Will it satisfy the ever increasing demands of global regulatory agencies? With increasing levels of Warning Letters and the like is your PQS at risk? How does your PQS compare with the best in class?

Over the last 25 years we have audited many thousands of quality systems, some bad, many good. We have also looked at how those in the aviation, micro-electronics and automobile industries manage quality. From this research we have identified industry best practices for quality management systems. This course will share these best practices and will help you to strike the right balance between compliance and effectiveness, and achieve operational excellence.

This course is a **'must attend'** if you are interested in having a pharmaceutical quality system that is compliant and cost effective!

Previous delegates on this course said:

"Good course. All important aspects are covered in very limited time, but with a depth that was very good."

Willeke van Tillburg-Kosman, MSD Animal Health Innovation, Norway

"Excellent course, recommended all QA site leaders should attend to drive change. Could have discussed for a week, but cannot be out of office for that long. Looking forward to taking back some new ideas – educators."

Rebecca Howells, BTG International, UK

Pharmaceutical Quality Systems: Best Industry Practices

12-13 November 2013
Manchester Marriott Victoria & Albert Hotel, Manchester, UK

Book now – limited places available
To reserve your place go to www.nsf-dba.com

PROPOSAL FOR A QUALIFIED PERSON IN THE NEW EUROPEAN REGULATION FOR MEDICAL DEVICES

By John Worroll

This Article describes the requirement for a 'Qualified Person' (QP) contained in the EU Commission Proposal for a new Regulation to cover medical devices and active implantable medical devices.

The Proposal is the result of long discussions between the Commission and stakeholders in the 27 Member States and aims to address the perceived weaknesses of the current Directives 93/42/EEC and 90/385/EEC.

The Proposal says that the QP should be responsible for regulatory compliance within a manufacturer's organisation and points out that a similar requirement exists within the EU legislation for medicinal products.

Some Member States (eg Germany) have a similar requirement in their local laws for medical devices.

REQUIREMENTS FOR A QP

Article 13.1 of the Proposal says that:

"Manufacturers shall have available within their organisation at least one qualified person who possesses expert knowledge in the field of medical devices."

It goes on to say that the expertise of the QP shall be demonstrated in one of two ways:

Either: "a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices."

Or: "five years of professional experience in regulatory affairs or in quality management systems relating to medical devices."

Another point to note is that the Proposal is quite explicit about the QP being "within the manufacturer's organisation" which appears to preclude the use of an external consultant. On the other hand, most manufacturers who are complying with the medical devices directives will already have, de facto, such a person within their organisation.

There are two minor derogations for manufacturers of custom made devices. Firstly, the experience requirement is reduced to two years regardless of academic qualification. Secondly, there is no need for custom manufacturers who are 'micro-enterprises' as defined by Regulation 2003/361/EC to have a QP.

ROLE AND FUNCTION OF A QP

The Proposal states that the QP is responsible for ensuring:

(a) that the conformity of the devices is appropriately assessed before a batch is released

(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date

(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled

(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

There is an analogy with the ISO 9001 and ISO 13485 requirement for a 'Management Representative':

"Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes… ensuring that processes needed for the quality management system are established, implemented and maintained."

In the case of the proposed Regulation, the function is to ensure and maintain regulatory compliance and in the case of the QMS standards, the function is to ensure and maintain the QMS.

Finally, the proposed Regulation states that:

"The qualified person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties."

This appears to mirror the QMS phrase 'irrespective of other responsibilities' in giving QPs freedom to discharge their responsibilities without fear or favour.

QUALIFICATIONS AND ANALOGY WITH THE PHARMACEUTICAL EQUIVALENT

It can be seen from the foregoing that, although the role and responsibility of the QP is similar in principle between the pharma and medical device worlds, the differences in detail are significant:

- The educational requirements are different in that the medical device QP can rely on professional experience alone
- Batch release is a major factor in the pharma world, but it plays a much smaller role in the medical device world. In practice the requirement for the QP to ensure that the "conformity of the devices is appropriately assessed before a batch is released" is probably more to do with ensuring that the conformity assessment has been properly carried out and that there is a quality system in place for product release rather than with physically releasing each batch

Because of these differences, it has been argued that the term 'QP' should be changed for medical devices to avoid confusion with and 'mission creep' towards the pharmaceutical term.

On the other hand, any medical device manufacturer wishing to comply with the Harmonised Standard for a quality management system, EN ISO 13485, will take note of the Human Resources requirement in para 6.2 that:

"Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience."

Manufacturers may therefore wish to implement a training programme to ensure their QPs have a good theoretical and practical knowledge of the regulations, covering the whole area rather than just relying on what they have picked up 'on the job'.

Roche Quality Certification Program (QCP)
– Helping Embed a Quality Culture in a Global Organisation

Looking back at the Pharma world over 2012 has shown that as an industry we still have many challenges ahead and improvements to make. Public health issues and regulatory enforcement actions still continue to make the headlines and show problems with quality management approaches and supply chains, all too often potentially putting patients at risk.

Why is this still the case in a mature industry sector, and what can we do to improve the situation?

Key factors now increasingly discussed at industry/regulatory events include the need to establish a 'quality culture' throughout an organisation, and to ensure that key staff throughout the operations, not just in the quality organisation, have the appropriate skills, knowledge and experience to make the right decisions – for the patient, for the business and for the regulators.

The Roche QCP, as reported in previous journals, continues to play a major part in helping Roche drive forward a culture of quality and continual improvement, aided by a growing network of QCP graduates across their global network.

2012 saw the successful completion of the fourth QCP based in the US, and the initial run of a parallel European-based QCP from Basel, Switzerland. QCP participation included attendees from the US, EU, Mexico, Brazil, Singapore, China and Japan.

Both Roche and NSF-DBA are proud of this program and the benefits it is providing to both the organisation and the participants. John Pinion, as Roche Senior Vice President for Global Quality & Compliance, continues to champion QCP with a strong personal vision, shared by many, that this is not a quick fix to a problem, but a proactive long-term commitment to the future of a strong quality culture in Roche.

The following comments came from the participants of the first Basel QCP class in 2012, who are pictured below with John Pinion *(front row, second from left)*.

"The program provided an excellent end to end overview and enhanced the understanding as well as critical thinking and discussions"

"One of the best trainings ever participated in!"

"The mixture of NSF-DBA lectures by experienced tutors and Roche SME presentations showing the company's approach was an excellent combination to ensure the most efficient training possible"

Contact Neil Wilkinson njw@nsf-dba.com if you wish to learn more about the types of in-house Quality Programs we are delivering for our key clients

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